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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,732	06/12/2001	Gary Bee	089498-0402	4949
20583	7590	12/18/2003	EXAMINER	
PENNIE AND EDMONDS 1155 AVENUE OF THE AMERICAS NEW YORK, NY 100362711			JOHANNSEN, DIANA B	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 12/18/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/880,732

Applicant(s)

BEE ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9 and 59-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 59-74 is/are rejected.
- 7) ☒ Claim(s) 1-6,9 and 59-74 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0803.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The following papers and materials have been entered:
  - a) the Preliminary Amendment filed September 17, 2001;
  - b) the Preliminary Amendment filed December 2, 2002;
  - c) the paper and computer readable forms of the Sequence Listing filed December 2, 2002; and
  - d) the Amendment and Provisional Election filed August 25, 2003.
2. Claims 1-6 and 9 have been amended, claims 7-8 and 10-58 have been canceled, and claims 59-74 have been added. Claims 1-6, 9, and 59-74 are now pending and under consideration.

### ***Election/Restriction***

2. Applicant's election of Group I in the Amendment and Provisional Election filed August 25, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). It is further noted that all non-elected claims have been canceled. Group I encompasses all of the claims now pending, specifically claims 1-6, 9 and 59-74.

### ***Specification***

3. The use of the trademarks GENBANK and AMPLITAQ has been noted in this application. The trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.
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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

***Drawings***

4. The drawings are objected to because Figure 6, as filed September 17, 2001, contains incomplete references to SEQ ID Nos. Specifically, the figure contains numerous references to "SEQ ID NO. \_\_\_\_". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. It is noted that as Applicant has amended the description of Figure 6 to provide the SEQ ID Nos corresponding to the sequences in Figure 6, no reference to the SEQ ID Nos is required in the Figure.

***Claim Objections***

5. Claims 1-6, 9, and 59-74 are objected to because of the following informalities: claim 1 in step (b) recites the language "one or more said particles" rather than, e.g., "said one or more particles" or "said one or more scattered-light detectable particles." Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1-6, 9, and 59-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 9, and 59-74 are indefinite over the recitation of the term "pharmacologically relevant gene." While the specification at page 15 provides a definition of the term "pharmacogenetically relevant," neither the specification nor the art provide a clear and limiting definition for the term "pharmacologically relevant." Accordingly, it is unclear as to what genes would be encompassed by this language, and particularly as to what types of genes "involved in drug metabolism" would be considered "pharmacologically relevant." Clarification is required.

Claims 1-6, 9, and 59-74 are indefinite over the recitation of the language "contacting the sample with a nucleic acid probe under differential hybridization conditions that allow said nucleic acid probe to hybridize specifically to a nucleic acid molecule comprising said target nucleotide sequence, wherein said nucleic acid probe or said nucleic acid molecule is labeled with one or more scattered-light detectable particles" in step (a) of claim 1. First, it is unclear as to whether the recitation "under differential hybridization conditions that allow said nucleic acid probe to hybridize specifically to a nucleic acid molecule comprising said target nucleotide sequence" merely constitutes a further limitation on the type of "hybridization conditions" employed in the claimed method, or whether this recitation actually requires the presence of the "nucleic acid molecule comprising said target nucleotide sequence." Second, to the extent that the claimed method may require the presence of the "nucleic acid molecule,"

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it is unclear as to whether the recited "nucleic acid molecule" is a molecule that may or may not be present in "the sample" (such that the practice of the method involves detecting the presence of a molecule that corresponds to the allele being detected), or whether the recited "nucleic acid molecule" is a reagent that is combined with the sample and the probe. Clarification is required.

Claims 1-6, 9, and 59-74 are indefinite over the recitation of the limitations "said hybridized nucleic acid molecules" and "said particle" in step (b) of claim 1. There is insufficient antecedent basis for these limitations in the claims.

Claims 1-6, 9, and 59-74 are indefinite over the recitation of the term "non-evanescent wave light" in claim 1. Neither the specification nor the prior art provides a clear and limiting definition for this terminology, and it is well-known to those of skill in the art that light of various types and from various sources may be used in such a manner so as to produce an evanescent wave or field, or, alternatively, be used in such a manner so as not to produce such an evanescent wave or field. Accordingly, it is unclear as to what would constitute "non-evanescent wave light" within the context of the claims, and as to what types of light sources or method steps are excluded by this claim language. Particularly, it is unclear as to whether the claims are intended to be limited to the use of a particular type of light source, whether the claims are intended to exclude method steps in which light is used in such a way so as to produce an evanescent wave or field, in which the use of an evanescent wave or field as a beam in light scattering is excluded, etc. Accordingly, clarification is required.

Claims 1-6, 9, and 59-74 are indefinite over the recitation of the phrase “detecting light scattered by said one or more scattered-light detectable particles under said conditions as a measure of the presence of said allele in said sample.” It is unclear whether the language “as a measure of” indicates that, e.g., the amount of light produced is measured or quantitated in some manner, or whether this recitation is merely intended to indicate that the presence of scattered light is considered to be indicative of the presence of the allele. Clarification is required.

Claim 2 is indefinite over the recitation of the limitation “said nucleic acid molecule in said sample” because there is insufficient antecedent basis for this limitation in the claims. As discussed above, the claims as written do not actually recite or refer to a nucleic acid molecule that is “in said sample.”

Claims 4 and 68-69 are indefinite over the recitation of the limitation “said nucleic acid molecule comprising said target nucleotide sequence which is not labeled with scattered-light detectable particles” in claim 4, because there is insufficient antecedent basis for this limitation in the claims.

Claims 5-6 are indefinite over the recitation of the phrase “wherein said step (a) comprises contacting a plurality of different nucleic acid probes” in step 5. First, the claim does not indicate with what the “plurality of different nucleic acid probes” is contacted. Second, it is unclear as to whether the “plurality of different nucleic acid probes” is a further limitation of the previously recited “nucleic acid probe” (such that the plurality of probes are capture probes that are “not labeled with scattered-light detectable particles” as required by claim 3), or whether the “plurality of different nucleic

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acid probes” of claim 5 are separate and distinct from the single “nucleic acid probe” previously recited in the claims.

Claims 9 and 59-67 are indefinite over the recitation of the limitation “said nucleic acid molecules that comprise said target nucleotide sequence” in claim 9 because there is insufficient antecedent basis for this limitation in the claims.

Claims 59 and 63-67 are indefinite over the recitation of the limitation “said labeling step” in claims 59, 63-65 and 67 because there is insufficient antecedent basis for this limitation in the claims. This rejection could be overcome by amending the claims to recite “said labeling” in lieu of “said labeling step.”

Claims 62 and 65 are indefinite because it is unclear how the claims are further limiting of claim 61 to the extent that claim 61 may be limited to bromodeoxyuridine (and thus not involve a “hapten-derivatized nucleotide”). This rejection may be overcome by amending claim 62 to recite “The method of claim 61, wherein said incorporated moiety is said hapten-derivatized nucleotide, and wherein said hapten-derivatized nucleotide is...”.

Claim 66 is indefinite over the recitation of the limitation “said target nucleotide sequence labeled with bromodeoxyuridine” because there is insufficient antecedent basis for this limitation in the claims.

Claims 68-69 are indefinite over the recitation of the limitation “said step of contacting the sample with a capture probe” because there is insufficient antecedent basis for this limitation in the claims. This rejection could be overcome by amending the claims to recite “said contacting the sample with a capture probe.”



Claim 74 is indefinite over the recitation of the language "further comprising the step of demonstrating that nucleic acid sequence from CYP2D7 pseudogene, CYP2D8 pseudogene, or both is not detected." First, there is insufficient antecedent basis for the limitation "the step of demonstrating." Second, it is not clear whether the recitation "that nucleic acid sequence from..." is intended to refer back in some manner to the previously recited language "nucleotide sequence that is unique to" an allele (such that the claim requires, e.g., the absence of sequences unique to the recited pseudogenes), or whether this language is intended to indicate more generally that no nucleic acid sequence of any kind from the recited pseudogenes is detected. Thus, the types of sequences excluded by this claim language cannot be determined. Clarification is required.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761 through January 13, 2004, and 571/272-0744 beginning January 14, 2004. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152 through January 13, 2004, and 571/272-0745 beginning January 14, 2004. The fax phone number for the organization where this application or proceeding is assigned is 703/872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long horizontal line extending to the right.

Diana B. Johannsen  
December 12, 2003